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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,796	12/04/2001	Eija Pirhonen	01942-00007	9843

22910 7590 03/09/2006

BANNER & WITCOFF, LTD.
28 STATE STREET
28th FLOOR
BOSTON, MA 02109-9601

EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/006,796

Applicant(s)

PIRHONEN ET AL.

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Acknowledgment of Papers Received: Request for Continued Examination dated 12/15/05.

Notice: The proposed Examiner's Amendment has been vacated since new art and grounds of rejection have been found. The new rejections are as follows:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1,9 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for N—methyl-2-pyrrolidone, does not reasonably provide enablement for all plasticizers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims broadly recite all plasticizers yet not all plasticizers would be capable of fulfilling the purposes of the invention. Quoted from *In re Wands*:(A) **The breadth of the claims**; the claims are drawn to an implant comprising any and all plasticizers; (B) **The nature of the invention**; the nature of the invention is that of a biodegradable implant; (C) **The state of the prior art**; the state of the prior art establishes that only particular plasticizers should be used for implant technology as seen by Dunn et al (USPN 5,702,716); (D) **The level of one of ordinary skill**; the level of ordinary skill in the art is high; (E) **The level of predictability in the art**; the level of predictability is high, since the properties of solvents, and plasticizers are well known in the art, (F) **The amount of direction provided by**

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the inventor; the inventor directs one or ordinary skill in the art only toward N-methyl-2pyrrolidine in the examples and specification, (G) **The existence of working examples**; the examples exemplify only N-methyl-pyrrolidone and make no mention of other plasticizers fitting the limitations of the claim or being useful in the invention, (H) **The quantity of experimentation needed to make or use the invention based on the content of the disclosure**; the artisan of ordinary skill would have to use trial and error with every known plasticizer in order to find one that exited upon contact with tissue fluids. From the large amount of known plasticizers and like compounds it would cause an undue burden on the artisan of ordinary skill in the art, to properly make and use the invention. Clarification and amendment to the claims and/or specification is required.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dunn et al (USPN 5,702,716 hereafter '716). The claims are drawn to a biodegradable implant comprising a rigid matrix, a plasticizer and a biologically active agent. The plasticizer exits the matrix upon contact with biological fluids. The claims also recite a method of manufacture including forming the implant and allowing it to solidify before implantation.

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3. The '716 patent teaches a solid biodegradable implant comprising a biodegradable thermoplastic polymers, such as polylactides, (claim 1) a plasticizer such as N-methyl-2-pyrrolidone (col. 5, lin. 30-33, examples), and growth factors for promoting tissue growth such as fibronectin and human growth factor (col. 10, lin. 63-col. 11, lin. 10). The implant is formed externally, where the plasticizer substantially exits the implant matrix upon exposure to water in a biological environment (col. 6, lin. 1-9). Upon exiting the matrix will stiffen and form the polymer system having the bioactive agents material within the solid polymer matrix (col. 5, lin. 1-13). The implant is porous (col. 9, lin. 8-67). The examples teach process of making the implants of the '716 patent comprising selecting a biodegradable polymer, adding a plasticizer and forming an implant (examples). Theses disclosures meet the limitations of claims 9-17 of the instant application.

4. Claims 1-8 are drawn to an implant produced by a particular process. The need result is seemingly identical to that of the '716 patent, namely a solid rigid, porous implant comprising a biodegradable polymer and an active agent entrapped therein. However the product claims recite process limitations as to the composition of the starting product and how the final product comes into being. These limitations render the claim product-by-process claims, thereby rendering the process limitation weightless regarding the patentability of the claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

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5. For these reasons the prior art anticipates the claims.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459

(1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. As discussed above claims 1-17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dunn et al (USPN 5,702,716 hereafter '716). As discussed above the claims are drawn to an implant and method of manufacturing the implant.

9. The '716 teaches and discloses both liquid and solid, porous implant compositions. The liquid implant formulation can solidify in vivo, releasing plasticizer once it makes contact with tissue fluids. During this process, the solidification, though fast acting will not be instantaneous. Thus at some point there will be a rigid, solid, flexible matrix comprising a plasticizer that is exiting the matrix leaving porous opening. This exiting will result in a stiffer implant, thus the implant will have a lower bending resistance prior to the insertion of the implant. Thus it is the

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position of the Examiner that though the '716 patent does not explicitly state a rigid matrix contain a plasticizer and polymer, due to the nature of the coagulation process required by the implant of the '716 patent a rigid matrix implant comprising a polymer and plasticizer will be created as an intermediate product of the prior art invention.

10. Further claims 1-8 are deemed product-by-process claims, meaning their process limitations will not be given patentable weight with regard to the patentability of the product being claimed. The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. See *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. See *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983). The '716 patent discloses a rigid matrix comprising a biodegradable polymer and plasticizer as an intermediate product of the invention, during the coagulation of the implant.

11. Regarding the process claims, the final product of the '716 is identical to the product claimed in the instant invention. Namely, a biodegradable porous implant comprising bioactive agents. The process of the instant invention, comprising finding a polymer, combining it with a plasticizer and allowing it exit when in contact with tissue fluids. This process occurs in the '716 patent in each of the examples. Regarding claims reciting specific instances the plasticizer is added, it is the position of the Examiner that since the final products are the same the order of

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steps inconsequential, unless evidence to the contrary can be provided. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

12. With these things in mind it would have been obvious follow the teachings of the '716 patent in order to produce a rigid matrix implant useful in tissue regeneration. It would have been obvious to follow these teachings and suggestions with an expected result of a porous implant good for tissue regeneration.

Response to Arguments

13. Applicant's arguments with respect to claims 1-17 have been considered but are moot in view of the new ground(s) of rejection. Although the '716 patent is a new grounds of rejection, the claims are rejected for the same reason. The claims are drawn to an intermediate product of the '716 patent. Applicant argues that the pore structures of the prior art and the '716 patents are different however this is not claimed. Applicant points to pictures explaining these differences however these pictures are blurry and no reasonable determination can be made. Applicant argues that beginning products differ, and that the plasticizer is merely coated in the plasticizer, yet again these limitations are not represented in the claims. Applicant further argues that only

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the surface is porous, while the claims are open to include the entire structure. These limitations should be incorporated into further iterations of the claims in order to overcome the art of record. The claims will remain rejected until such limitations can be implemented.

Correspondence

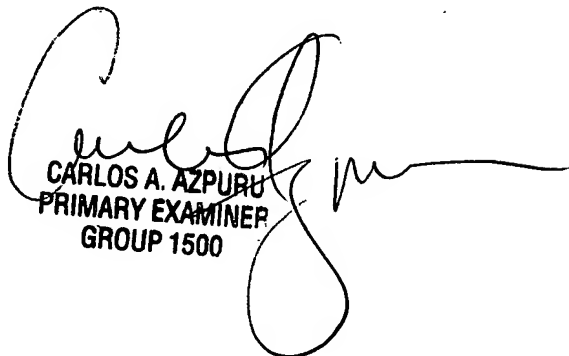
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MP Young

Micah-Paul Young
Examiner
Art Unit 1618


CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500